DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Advisory Committee; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee on September 2–3, 1999. The meeting will be held at the National Institutes of Health, Building 31C, 6th Floor, Conference Room 10, 9000 Rockville Pike, Bethesda, Maryland 20892, starting on September 2, 1999, at approximately 9:00 a.m., and will recess at approximately 5:00 p.m. The meeting will reconvene on September 3, 1999, at approximately 8:30 a.m. and will adjourn at approximately 5:00 p.m. The meeting will be held to discuss Proposed Actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496) and other matters to be considered by the Committee. The Proposed Actions will follow this notice of meeting. The meeting will be open to the public. Attendance by the public will be limited to space available.

Debra W. Knorr, Deputy Director, Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone (301) 496–9838, FAX (301) 496–9839, will provide a summary of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Knorr in advance of the meeting. The Office of Recombinant DNA Activities (ORDA) web site is located at *http://www.nih.gov/od/orda* for further information about the office.

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: July 27, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Recombinant DNA Activities; Recombinant DNA Research: Proposed Actions Under the NIH Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of Proposed Actions Under the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).*

SUMMARY: This notice sets forth proposed actions to the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* (59 FR 34496, amended 59 FR 40170, 60 FR 20726, 61 FR 1482, 61 FR 10004, 62 FR 4782, 62 FR 53335, 62 FR 56196, 62 FR 59032, 63 FR 8052, 63 FR 26018, 64 FR 25361). These proposed actions will be considered by the Recombinant DNA Advisory Committee (RAC) during its September 2–3, 1999, meeting. Public comments and any recommendations made by the RAC on these proposed actions will be considered by the NIH Director. Decisions regarding these proposed actions will be issued in accordance with the *NIH Guidelines*, as deemed appropriate by the NIH Director.

DATES: Interested parties are invited to submit comments concerning the proposed actions. Comments received by August 25, 1999, will be reproduced and distributed to the RAC for consideration at its September 2–3, 1999, meeting. After consideration of this proposal and comments by the RAC, the NIH Director will issue decisions in accordance with the *NIH Guidelines.*

PUBLIC COMMENTS: Interested parties are invited to comment on these proposed actions. Written comments should be submitted to: Debra Knorr, RAC Executive Secretary, Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, or by FAX to (301)–496–9839. Written comments received by August 25, 1999, will be reproduced and distributed to the committee members for their consideration during the September 2–3, 1999, RAC meeting. All comments received in response to this notice will be considered by the RAC and will be available for public inspection in the above office on weekdays between the hours of 8:30 a.m. and 5:00 p.m.

CONTACT INFORMATION: For further information regarding these proposed actions please contact: The Office of Recombinant DNA Activities (ORDA), National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone: 301–496–9838, Facsimile: 301–496–9839. Additional information is also available at ORDA's web site: *http://www.nih.gov/od/orda*.

SUPPLEMENTARY INFORMATION: The NIH has continually refined its oversight of human gene transfer research as the field has developed. In December 1996, the RAC review process was modified to consist of a rapid initial analysis of each human gene transfer experiment to determine which protocols present significant novel scientific, safety, ethical, legal and/or social issues and therefore warrant further RAC review and public discussion. In October 1997, the *NIH Guidelines* were amended to eliminate the requirement for approval by the RAC of individual protocols. The objectives of both of these actions were to streamline the review process and ensure that the roles and responsibilities of the NIH complement, rather than duplicate, those of other Federal agencies while preserving public confidence in the field.

At present, human gene transfer protocols must be approved by the local Institutional Biosafety Committee (IBC) and the local Institutional Review Board (IRB) prior to submission to the NIH Office of Recombinant DNA Activities (ORDA) for RAC review. Within 15 days of receipt of the complete submission to ORDA, investigators are informed of the RAC's decision as to whether a given protocol is novel and therefore warrants further review and public discussion. To provide adequate time for additional analysis of the protocol and public notice of the upcoming RAC review and discussion, a protocol must be received by ORDA at least eight weeks prior to